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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/997,588 | 11/29/2001 | Chen Xing Su | 10209.353 | 6233 |

21999 7590 01/24/2007
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| EXAMINER |
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LEITH, PATRICIA A

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| ART UNIT | PAPER NUMBER |
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1655

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/24/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-----------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/997,588 | SU ET AL. | |
| | Examiner | Art Unit | |
| | Patricia Leith | 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-23,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-12 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/06/06 has been entered.

Claims 1 and 5-28 are pending in the application.

Claims 13-23 and 27-28 were withdrawn on the merits as they are directed toward a non-elected invention.

Claims 1, 5-12 and 24-26 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-12 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been newly amended to recite: "filtering pressure may range between about". The language 'between about' is considered New Matter in that this phrase was not explicitly or implicitly taught by the Disclosure as originally filed. Paragraph [0034] of the Disclosure states: "from 0.1 psig up to about 1000 psig". It is suggested that Applicant to delete the recitation of 'between about' and amend claim 1 to recite "from 0.1 psig up to about 1000 psig" in order to overcome this rejection.

Because claims 5-12 and 24-26 depend directly or indirectly upon claim 1, claims 5-12 and 24-26 necessarily possess all of the limitations of claim 1 and thus, also contain New Matter and are properly rejected under this statute.

Claim Rejections - 35 USC § 103

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) and further in view of Gagnon (1997) in view of Elliot (US 1,885,401).

The teachings of Chye, Schechter and Gagnon were discussed keenly in previous Office Actions.

The claim now requires that the fruit is placed into plastic lined containers, mechanical separation of the seeds, peel, pulp and juice, and filtering via a centrifuge decanter with a screen filter size between 1 and 2000 microns at a pressure between .1 psig and 1000 psig. It is noted that a centrifuge decanter is also known as a 'centrifugal' or a centrifuge filter or a centrifuge filtration device (*inter alia*).

Elliot (US 1,885,401) discloses a conventional method for preparing fruit juices comprising mechanically separating the rind (skin/peel), seeds and pulp from the fruit, and clarification via centrifuge filtration (see, e.g., columns 1 and 2). Elliot taught that a

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filter of 80 mesh was suitable for separation of the pulp from the juice (see column 2).

80 mesh = 177 microns.

One of ordinary skill in the art would have been motivated to place MCJ in plastic lined containers in order to store the fruit prior to processing. This is considered an obvious step in that the ordinary artisan would have recognized that fruit is typically picked and placed in baskets or other types of vessels to transport to the place of processing. The choice of plastic lined containers would have been advantageous in order to keep pests from entering the containers in order to prevent spoilage of fruit.

One of ordinary skill in the art would have been motivated to separate the seeds/rind/pulp via mechanical separation including the use of a centrifuge decanter (centrifuge filtration) in order to clarify the juice for packaging. It was clear from Elliot that the use of these means to produce juice was well known and conventional in the art. Further, although Elliot did not specifically teach what mesh screen they used for the centrifugal filtration, it is clear that filtration sizes within the claimed range were well known to be used in the art. One of ordinary skill in the art would have been motivated to optimize the filter size as well as the pressure on the centrifuge (based in-part on the centrifugal force) in order to best clarify the juice without clogging the filter.

To reiterate, Chye clearly teach that people drank MC juice mixed with grape and blueberry juice. It is deemed, especially in view of Schechter, that when people ingested this juice, scavenging lipid hydroperoxides would have been an inherent

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consequence, since the product is the same and the patient (consumer) population is the same. Again, it is deemed that the processing steps for obtaining MC juice does not materially change the juice. It is also deemed that people naturally possess lipid hydroperoxides, and thus the act of drinking the juice disclosed by Chye of the prior art, would have inherently manifested the results of inhibiting/preventing/reversing lipid peroxidation.

Claims 1, 4-12 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) in view of Gagnon (1997) in view of Brock et al. (1991) in view of Nahir (EP 0 555 573 A1) and in view of Elliot (US 1,885,401).

The teachings of Chye, Schechter, Gagnon, Brock and Nahir were discussed in previous Office Actions. None of the references specifically taught wherein the fruit is placed into plastic lined containers, mechanical separation of the seeds, peel, pulp and juice, and filtering via a centrifuge decanter with a screen filter size between 1 and 2000 microns at a pressure between .1 psig and 1000 psig. It is noted that a centrifuge decanter is also known as a 'centrifugal' or a centrifuge filter or a centrifuge filtration device (*inter alia*).

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To reiterate, Elliot (US 1,885,401) discloses a conventional method for preparing fruit juices comprising mechanically separating the rind (skin/peel), seeds and pulp from the fruit, and clarification via centrifuge filtration (see, e.g., columns 1 and 2). Elliot taught that a filter of 80 mesh was suitable for separation of the pulp from the juice (see column 2). 80 mesh = 177 microns.

One of ordinary skill in the art would have been motivated to place MCJ in plastic lined containers in order to store the fruit prior to processing. This is considered an obvious step in that the ordinary artisan would have recognized that fruit is typically picked and placed in baskets or other types of vessels to transport to the place of processing. The choice of plastic lined containers would have been advantageous in order to keep pests from entering the containers in order to prevent spoilage of fruit. One of ordinary skill in the art would have been motivated to separate the seeds/rind/pulp via mechanical separation including the use of a centrifuge decanter (centrifuge filtration) in order to clarify the juice for packaging. It was clear from Elliot that the use of these means to produce juice was well known and conventional in the art. Further, although Elliot did not specifically teach what mesh screen they used for the centrifugal filtration, it is clear that filtration sizes within the claimed range were well known to be used in the art. One of ordinary skill in the art would have been motivated to optimize the filter size as well as the pressure on the centrifuge (based in-part on the centrifugal force) in order to best clarify the juice without clogging the filter.

Response to Arguments

Applicant's arguments were fully considered, but not found persuasive.

Applicant initially argues that the prior art of record does not teach the claimed embodiments (pp. 10-11, Remarks). This argument is moot in light of the introduction of Elliot (US 1,885,401).

Applicant argues that "the levels of lipidperoxidation inhibition experienced by utilizing the products and methods of the present invention are not merely intrinsic [sic] properties of Morinda citrifolia. The....in order to produce an improved Morinda citrifolia product, which has increased capacity to inhibit Lipiberoxidation [sic]" (p. 11, Remarks). However, this appears to be unsubstantiated allegation, as Applicant has not provided any convincing arguments nor evidence that would demonstrate that MCJ made by the claimed method would provide for 'increased capacity' of inhibiting lipidperoxidation. It remains deemed that the fruit juice as processed according to the claims is the same juice disclosed in the prior art, or so similar that no discernable differences could be made.

Applicant argues that "...TNJ...out performed other noni based juices in antioxidant studies performed in connection with this application" (p. 11, Remarks).

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However, it is clear on the record that TNJ was already known in the art and that people consumed this product for various ailments. The Examiner cannot clearly delineate the data present in the provisional application 60/251,417; however, even considering *in arguendo* that TNJ did 'out perform' other noni based juices, it is reiterated that TNJ was clearly used in the art prior to Applicant's earliest filing date. Again, TNJ contains MCJ, blueberry and grape juice. This product must have inhibited lipidperoxidation at the *same level* as indicated by provisional application 60/251,417 *because it is the same product*.

Applicant argues the references individually (p. 12, Remarks): In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues: "The composition as recited in the claims of the present invention has a scavenging effect which exceeds the regular intake of vitamin C and other known antioxidants" (p. 12, Remarks). However, the Examiner is not comparing the scavenging effect of MCJ to that of vitamin C or 'other antioxidants'. It was clear that TNJ containing MCJ, blueberry juice and grape juice was already known and consumed in the art. Therefore, the TNJ of the prior art must have had the same lipid scavenging effects of the TNJ as recited in Applicant's provisional application.

Applicant argues that Schechter "does not describe a method of processing and administering the noni fruit so as to provide a stronger scavenging effect.." (p. 12, Remarks). Again, Applicant is arguing one reference, wherein the rejection as a whole is made over several references rendering the claims *prima facie* obvious.

It is noted that although the claims state a method of processing and administering, each part of the claim; i.e., processing and administering separately, are considered obvious, and further the combination is therefore considered obvious.

Applicant states that the references are not enabling: "Chye and Schechter both indicate that Tahitian Noni juice was ingested, but neither prior art reference disclosed the method for production...the references do not place one skilled in the art in possession of the products which are discussed, and do not place one of skilled in the art in possession of all of the claim limitations of the present invention " (p. 13, Remarks). This argument is essentially rendered moot in light of the incorporation of Elliot into the rejection. However, it is noted that the references are enabled in that they disclosed Tahitian noni juice, which contained MCJ, blueberry and grape juice which was well known to be consumed. Lipid scavenging must have been an intrinsic consequence of the ingestion of this juice, and it must have scavenged lipids at the same intensity as that of the TNJ of the Instant specification in that they are deemed the same product. The particular manufacturing methods are deemed to be obvious in light

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of the combination of the references. Again, it is deemed that the manufacturing methods as claimed would have produced MCJ which would have been the same, or so similar to MCJ of the prior art that no discernable differences could be established. Applicant has not provided any evidence that the juice manufactured by the process as recited in the claims has any unexpected results over MCJ or TNJ of the prior art.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

January 15, 2006

A handwritten signature in black ink, appearing to read 'Patricia Leith', written in a cursive style.